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**ABSTRACT:**

A bag assembly eg a urine leg bag 1 is formed of two sheets 10 and 11 welded together around their edge, and an inlet tube 2 of a soft, flexible material eg PVC with its end secured between the two sheets at one edge. To strengthen the inlet tube during the welding operation, a sleeve 4 of e.g. a stiffer PVC is inserted in the end of the tube. A flutter valve 5 may be assembled on the end of the tube so that it is held in place by the two sheets when welded together. An outlet tube 3 is joined to the bag 1 at an opposite edge.

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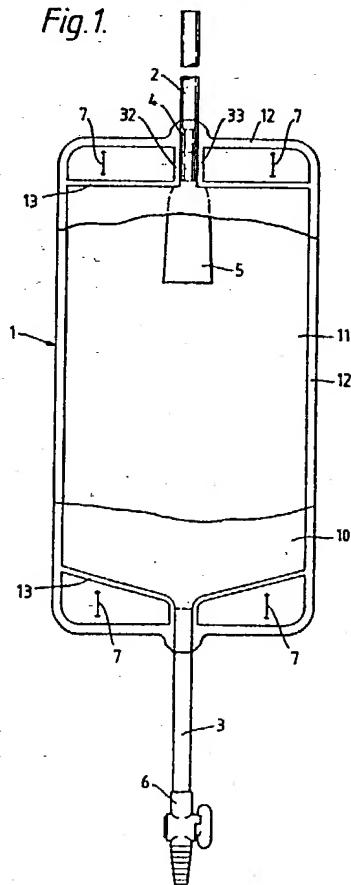
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## (54) Medico-surgical bag assembly

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Fig. 1.

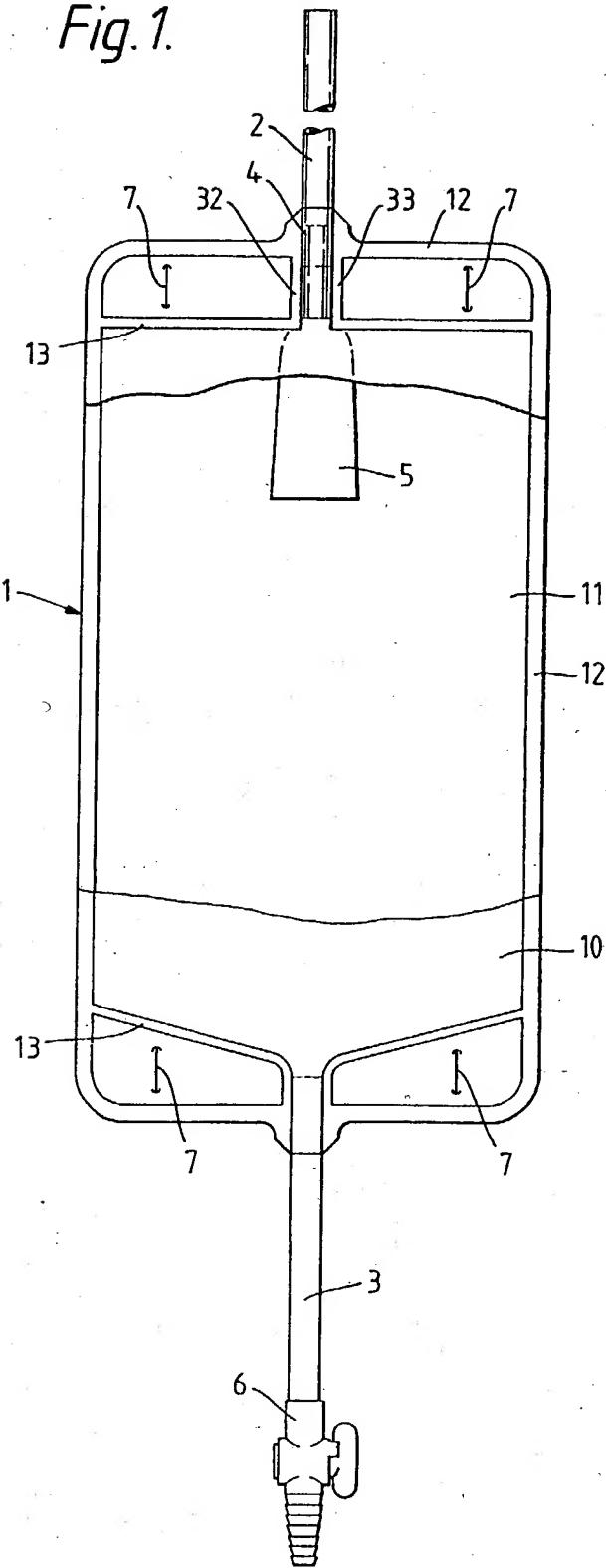


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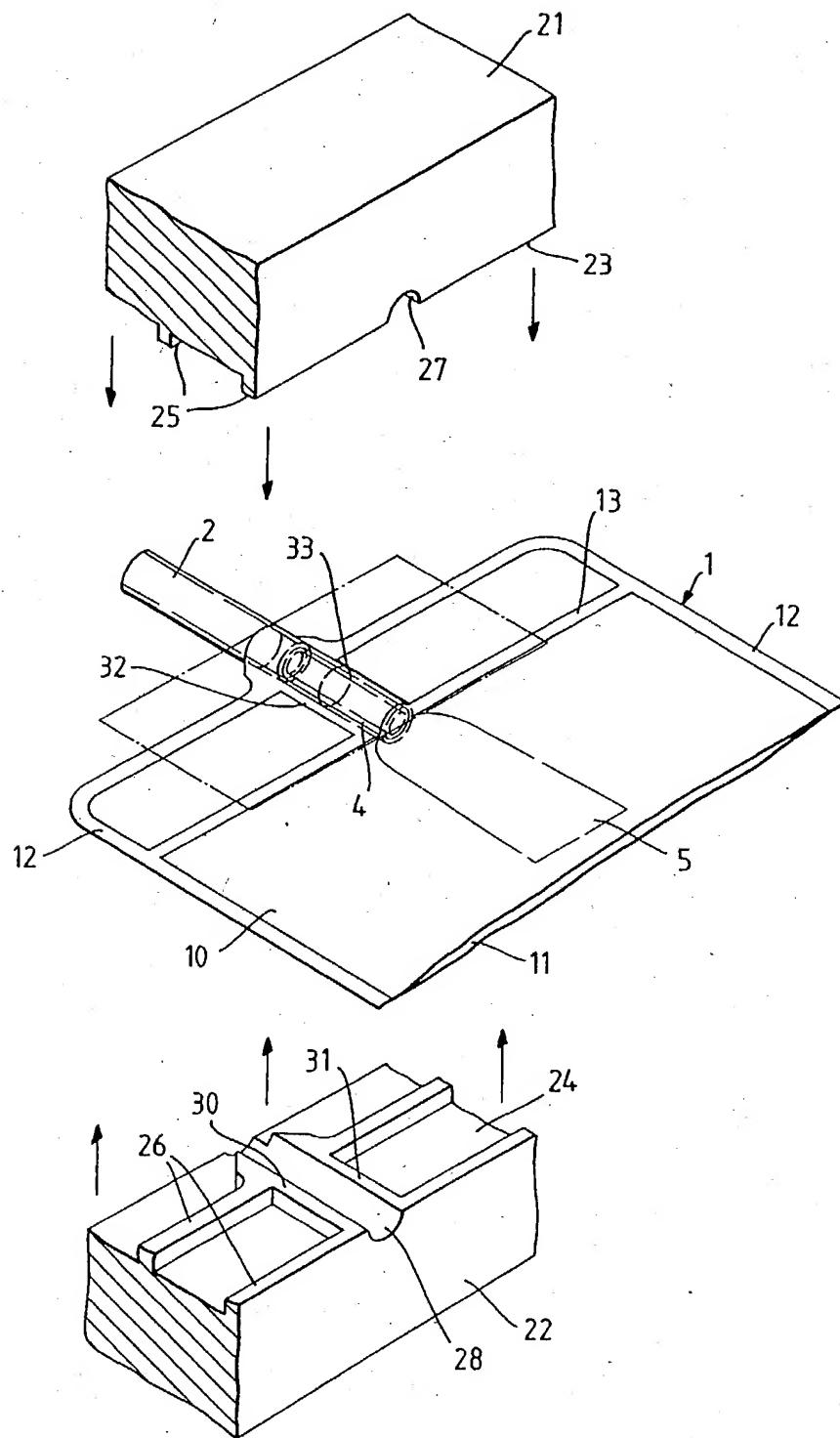
Fig. 1.



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Fig. 2.



**SPECIFICATION****Medico-surgical bag assemblies and their manufacture**

- 5 This invention relates to medico-surgical bag assemblies and their manufacture.
- The invention is more particularly, but not exclusively concerned with urine bag assemblies and with manufacturing methods by which the inlet tube can be secured to such bags.
- With various medico-surgical bags (for collecting or holding fluids for subsequent dispensing), but in particular with urine bags, it is desirable to join soft, flexible, kink-resistant tubing to a bag opening. With urine leg bags, the bag is hung under the user's clotting in an inconspicuous position alongside his leg. The bag may be hung close to the upper or lower end of the user's leg according to the user's preference. The inlet tubing connected to the urine bag must thereby be capable of being bent to accommodate the user's movement whilst ensuring that the bore along the tubing remains open. Because of the prolonged use of the urine bags the tubing should also be as soft as possible to avoid discomfort to the user.
- 30 The urine bags themselves are made by edge welding together two sheets of a flexible plastics material such as PVC. The material selected must be capable of containing the urine without allowing the escape of odours and must be suitable for heat welding in order to ensure that the bag can be made at low cost for single-use applications. The inlet tubing is commonly secured to the bag between the two sheets when they are welded together.
- A problem with such a construction arises because the welding process used to join the tubing to the bag can cause the tubing to collapse into a figure-of-eight shape if the tubing is of a soft material. This can allow leakage between the tubing and the sheets of the bag at the waist of the eight shape. To avoid this, it has been the practice to use stiffer tubing capable of withstanding the welding process, but thereby making the tubing less comfortable to the user.
- It is an object of the present invention to enable soft tubing to be used without the risk of leakage.
- 55 According to one aspect of the present invention there is provided a medico-surgical bag assembly comprising a bag having first and second sheets of a flexible plastics material joined together around their edge, and a length of soft flexible tubing joined to said bag to open therein by heat welding said first and second at an edge thereof about said tubing, wherein the tubing includes a sleeve of reinforcing material located therein in the region only of the weld such as to stiffen said tubing in the region of the weld and thereby maintain the shape of the tubing during the welding.
- The tubing is preferably of a plastics material and may be of a PVC material. The sleeve is preferably of a plastics material and may be of a PVC material harder than the material of the tubing. The sleeve may be solvent bonded into said tubing.
- 70 The assembly preferably includes a flap valve secured on said tubing under the said sheets.
- The assembly preferably includes outlet means located in said bag assembly at an edge of said bag opposite the said edge at which said tubing is joined to said bag.
- 80 The assembly may be a urine leg bag assembly, the flexible tubing providing an inlet of urine to said bag.
- 85 According to another aspect of the present invention there is provided a method of manufacturing a medico-surgical bag assembly comprising the steps of inserting a sleeve of reinforcing material in one end of a length of soft flexible tubing, placing the said one end of the tubing between the edges of first and second sheets of flexible plastics material, heat welding the edges of the two sheets together about the end of the tubing as thereby to produce a bag sealed about its edge into which the said tubing opens.
- The method may include the step of placing a flap valve on the said one end of said tubing prior to placing the tubing between the edges of the sheets such that the valve is secured in place when the sheets are welded together and such that the valve projects within the bag.
- 100 According to a further aspect of the present invention there is provided a medico-surgical bag assembly made by a method according to the above other aspect of the present invention.
- 105 A urine leg bag assembly and its manufacture in accordance with the present invention, will now be described, by way of example, with reference to the accompanying drawings, in which:
- 110 *Figure 1* is a partly cut away plan view of the assembly; and
- 115 *Figure 2* is a perspective view showing a part of the assembly during manufacture.
- With reference to Fig. 1, the assembly comprises a urine bag 1, an inlet tube 2, an outlet tube 3.
- 120 The urine bag 1 is of generally rectangular shape being 278mm long by 140mm wide and is formed from two sheets 10 and 11 of flexible transparent textured PVC such as Fro-mocene (a trade mark of ICI) having a thickness of about 0.2mm. The two sheets are heat welded together about their outer edge 12 to seal the bag. A backing sheet, not shown, is joined to one face of the bag, the sheet being of a material that is comfortable
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next to the skin. The bag 1 is formed with slits 7 for receiving straps by which the bag can be secured to the patient's leg.

The inlet tube 2 is of a soft, flexible, kink-resistant elastomeric plastics material such as plasticised PVC and is typically about 500mm long. The lower end of the inlet tube 2 is joined to the upper end of the bag between the two sheets 10 and 11, in a manner that 10 is described in detail below. The lower end of the tube 2 projects into the bag by a distance of about 28mm, the two sheets 10 and 11 being secured together by an additional lateral weld line 13 close to the lower end of the 15 tube 2 of opposite sides of the tube. A reinforcing sleeve 4 of length about 30mm is located within the tube 2 at its lower end to give the tube additional stiffness in the region of the welded junction with the bag. The 20 sleeve 4 is of a plastics material, such as a less plasticised PVC, that is harder than the inlet tube 2, and is solvent bonded or is a push, slide fit in the tube. At its lower end, the tube 2 supports a one-way flap valve 5 25 that is fitted on the outer surface of the tube, between the tube and the overlying sheets 10 and 11. The flap valve 5 is of conventional form being made of two flexible plastics sheets that normally lay flat against one 30 another, but which are opened by fluid flowing between them from the tube 2 and closed more firmly together, to seal the forward end of the tube closed by pressure within the bag 1. The purpose of the flap valve 5 is to prevent reflux of urine from the bag along the 35 inlet tube 2 if, for example, the bag is inadvertently squeezed or inverted.

The outlet tube 3 is typically 100mm long, of which 23mm at its upper end is secured in 40 the bag 1 between the two sheets 10 and 11 in the same way as with the inlet tube 2. The outlet tube 3 is also of a PVC and may be of a stiffer grade, since it is of shorter length and hangs straight down from the bag for the 45 purpose of discharging it as necessary. The lower end of the outlet tube 3 is terminated by an on/off drain tap 6 which is normally closed, but which can be opened to enable the contents of the bag to be drained.

50 The assembly is manufactured in the manner shown in Fig. 2. The reinforcing sleeve 4 is inserted in the lower end of the inlet tube 2, after coating with the solvent (if used). The upper end of the flap valve 5 is then pushed 55 over the lower end of the inlet tube 2 by a distance of about 20mm. The lower end of the inlet tube 2 is then laid between the two sheets 10 and 11 forming the bag 1, so that the upper part of the flutter valve 5 lies under 60 the sheets 10 and 11. The outlet tube 3 (not shown in Fig. 2) is similarly laid between two sheets 10 and 11 at the opposite end of the bag 1, but this tube 3 does not require a reinforcing sleeve because of the inherently 65 stiffer nature of the outlet tube. The compo-

nent parts of the bag assembly are positioned between upper and lower welding electrodes 21 and 22. The electrodes 21 and 22 are shaped on their opposing faces 23 and 24 70 with a pattern of ridges 25 and 26 corresponding to the weld lines to be produced on the bag. Each electrode is also provided with a channel 27 and 28 of semicircular section defined between two walls 30 and 31 which 75 receive the lower end of the inlet tube 2. A similar surface formation is provided to receive the outlet tube 3.

The two electrodes 21 and 22 are brought together, trapping the tubes 2 and 3 between 80 them, and heat is then applied by RF power to electrodes thus causing the material of the sheets 10 and 11 to reach melt temperature. On removal of RF power the material resolidifies to create the weld. A welded outer edge 85 12 is formed around the bag 1 together with additional lateral weld lines 13 across the ends of the bag in the region of the end of the two tubes. The walls 30 and 31 of the electrodes produce weld lines 32 and 33 between the two sheets 10 and 11 along the 90 length of the lower end of the inlet tube, whilst the channels 27 and 28 cause the sheets to be tightly secured to the tube 2 and the reinforcing sleeve 4 to be welded into the 95 tube 2. The reinforcing sleeve 4 acts, during the welding process, as an internal support mandrel for the tube 2, thereby preventing it from being deformed by the pressure and heating effects of the welding electrodes, and 100 remains as a part of the bag after welding. The outlet tube 3 is similarly joined in the bag 1, but without the need for the reinforcing sleeve used in the inlet tube. The slits 7 are formed at the same time as the welded regions, between the lateral weld line 13 and the outer weld 12 along the end of the bag.

105 It can be seen that the use of a reinforcing sleeve 4 within the end of the inlet tube 2 enables a secure leak-proof weld to be produced with a tube of a relatively soft material thereby enabling a urine bag assembly to be produced at low cost which is comfortable to use for long duration.

110 It will be appreciated that other medico-surgical bag assemblies could be produced in the same way.

#### CLAIMS

1. A medico-surgical bag assembly comprising a bag having first and second sheets of a flexible plastics material joined together around their edge and a length of soft flexible tubing joined to said bag to open therein by heat welding said first and second sheets at 120 an edge thereof about said tubing, wherein the tubing includes a sleeve of reinforcing material located therein in the region only of the weld such as to stiffen said tubing in the region of the weld and thereby maintain the 125 shape of the tubing during the welding.

2. A medico-surgical bag assembly according to Claim 1, wherein the said tubing is of a plastics material.
3. A medico-surgical bag assembly according to Claim 2, wherein the said tubing is of a PVC material.
4. A medico-surgical bag assembly according to any one of the preceding claims, wherein the said sleeve is of a plastics material.
5. A medico-surgical bag assembly according to Claim 4, wherein the sleeve is of a PVC material and is harder than the material of the tubing.
6. A medico-surgical bag assembly according to any one of the preceding claims, wherein the sleeve is solvent bonded into the said tubing.
7. A medico-surgical bag assembly according to any one of the preceding claims, wherein the assembly includes a flap valve, and wherein said flap valve is secured on said tubing under the said sheets.
8. A medico-surgical bag assembly according to any one of the preceding claims, wherein the said sheets are of a PVC material.
9. A medico-surgical bag assembly according to any one of the preceding claims including outlet means located in said bag assembly, and wherein said outlet means is located at an edge of said bag opposite the said edge at which said tubing is joined to said bag.
10. A urine leg bag assembly according to any one of the preceding claims, wherein the said flexible tubing provides an inlet of urine to said bag.
11. A medico-surgical bag assembly substantially as hereinbefore described with reference to the accompanying drawings.
12. A method of manufacturing a medico-surgical bag assembly comprising the steps of inserting a sleeve of reinforcing material in one end of a length of soft flexible tubing, placing the said one end of the tubing between the edges of first and second sheets of flexible plastics material and heat welding the edges of the two sheets together about the end of the tubing such as thereby to produce a bag sealed about its edge into which the said tubing opens.
13. A method according to Claim 12, including the step of placing a flap valve on the said one end of said tubing prior to placing the tubing between the edges of the sheets such that the valve is secured in place when the sheets are welded together and such that the valve projects within the bag.
14. A method substantially as hereinbefore described with reference to the accompanying drawings.
15. A medico-surgical bag assembly made by a method according to any one of the Claims 12 to 14.
16. Any novel feature or combination of

features as hereinbefore described.

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